Reimbursement Steering Committee
Highlights of 2006 Proposed Rule
for Outpatient Prospective Payment System

Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule [Federal Register / Vol. 70, No. 141 / Monday, July 25, 2005 / pp**.** 42674-42763]

Refer to the full text of the Proposed Rule for more information

Comments on the Proposed Rule must be received by 5 PM September 16, 2005

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I. Background (pp. 42676)

Refer to Proposed Rule.

II. Proposed Updates Affecting Payments for CY 2006 (pp. 42680 – 42703)

A. Recalibration of APC Relative Weights for CY 2006

CMS is required to review and revise the APC relative weights at least annually. For 2006, CMS is proposing that the APC relative payment weights continue to be based on the median hospital costs for services in the APC groups. APC relative weight recalibrations would be based on CY 2004 claims data.

"Pseudo" Single Claims Process

CMS is proposing to continue to set the median APC relative payment weights using single procedure claims. CMS received comments on their final rule for 2005 that using single procedure claims results in basing payments on the least costly services. CMS agrees that it is desirable to include as many claims as possible in the analysis, but has used only single procedure claims because it is difficult to appropriately allocate packaged costs for multiple procedure claims.

Since 2003, CMS has been looking at their data to find ways to include more claims with multiple procedures in their APC relative weight calculations. In 2005, to include some multiple procedure claims in their calculations, CMS identified 383 codes that they believed had limited packaged costs. CMS bypassed these HCPCS codes when billed with another separately payable HCPCS code and considered these claims to be "psuedo" single claims for inclusion in the APC relative weight calculations.

For 2006, CMS is proposing to bypass 404 codes that they believe have limited packaged costs (Table 1, pp. 42682-42688) to create "psuedo" single claims to be used in the APC relative weight calculations. Including the "pseudo" single claims in their calculation of APC relative payment weights would result in including 81 million claims in the calculation of the 2006 APC relative weights. The data would include 50 million "pseudo" single bills and 31 million "natural" single bills (bills that were submitted containing only one separately payable major HCPCS code).

CMS requested input on the "pseudo" single claim process, the bypass list, and the criteria for including codes on the bypass list.

Proposed Calculation of Median Costs for 2006

This section includes a detailed explanation of CMS's proposed calculation of median costs which was used in calculating the proposed rates in Addendum A and Addendum B. It explains how CMS excluded claims data for hospitals and services not paid under OPPS, claims with multiple procedures that could not be converted to "pseudo" single claims, and claims excluded for other reasons (such as aberrant and outlier data and claims with token charges).

It explains how CMS assigned packaged costs with multiple procedure claims included in the calculation. When one of the two separately payable procedures on a multiple procedure claim was a bypass code, CMS split the claim into two single procedure claims records and the packaged costs were included with the code that was not on the bypass list.

This section also describes how CMS used cost-to-charge ratios (CCR) in their calculations. CMS only used cost reports for hospitals that filed outpatient claims in CY 2004. CMS calculated the CCRs for each hospital at the department and overall level using the most recent cost report available. CMS excluded outlier CCRs at the department level. For 2006, CMS is proposing to eliminate aberrant CCRs from high volume hospitals because these CCRs might skew the data.

As has been the policy since OPPS implementation, CMS applied a geographic wage adjustment to 60 percent of the cost of the claim (the portion CMS previously determined to be labor-related).

This section also includes a list of proposed packaged services by revenue code (table 2, page 42690).

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Proposed Calculation of Scaled OPPS Payment Weights
CMS calculated the proposed relative payment weights for each APC using the calculated median cost of the APC scaled to the mid-level clinic visit APC 0601. Each APC's relative weight was calculated by dividing the APC's median cost by the median cost for APC 0601 ($60.57 for CY 2006). Based on this calculation, the relative payment weight for APC 0601 is 1.00 ($60.57 / $60.57), and the relative payment weight for an APC with a median cost of $181.71 would be 3.00 ($181.71 / $60.57).

CMS is required to implement the APC recalibrations, wage index changes and other adjustments budget neutrally. Charges for brachytherapy are excluded from budget neutrality calculations.

Proposed Changes to Packaged Services
In response to public requests, CMS created a Packaging Subcommittee to the APC Panel. The subcommittee reviews packaged services to identify codes they believe require significant hospital resources and could frequently be provided to patients as the sole service on a given date.

The APC Panel made several recommendations regarding changes to packaged services based on the subcommittee report. The recommendations and CMS's proposal are outlined in the table below.

APC Panel Recommendation	CMS Proposal
The Panel recommends that CMS assign a modifier to be used with the following codes when no other services are reported on the same day: • 36540 (collect blood venous device) • 36600 (withdrawal of arterial blood) • 51701 (insertion of non-indwelling bladder catheter)	CMS is proposing: • not to adopt the modifier recommended by the APC panel. • to maintain packaged status for 36540 and 36600. • to pay separately for 51701, 51702 and 51703 and add these codes to the bypass list.
The Panel recommends that CMS maintain the current packaged status for: • 76937 (ultrasound guidance for vascular access) • 77790 (radiation handling) • 94760 (pulse oximetry for oxygen saturation, single determination) • 94761 (pulse oximetry for oxygen saturation, multiple determinations)	CMS is proposing to accept the APC Panel recommendation to leave the following codes packaged: 76937, 77790, 94760, 94761.
The Panel recommends that CMS allow separate payment for 90471 and 90472, consistent with other injection codes	See Section VIII for CMS proposal.
The Panel recommends that CMS gather more data for review of the following codes: • 94762 (overnight pulse oximetry) • 42550 (injection for salivary x-ray) • 38792 (sentinel node imaging)	CMS is proposing to accept the APC Panel recommendation to gather data and review codes 94762, 42550, and 38792

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CMS encourages the public to submit information about common clinical scenarios involving currently packaged codes to the Packaging Subcommittee for its ongoing review. Detailed suggestions can be submitted to APCPanel@cms.hhs.gov, with "Packaging Subcommittee" in the subject line.

B. Proposed Payment for Partial Hospitalization

If CMS were to use the same update methodology used for CY 2005 to calculate the 2006 per diem rates for partial hospitalization services, the combined hospital-based and community mental health center (CMHC) median per diem cost would decrease 48 percent. CMS believes the resulting per diem rates would be too low to cover the costs for all partial hospitalization programs and is therefore considering alternate update methodologies. CMS describes two alternatives, one which excludes CMHC data and another that applies a trimming methodology to CMHC data.

CMS would prefer using both CMHC and hospital data to establish the rates, but CMHC data has been extremely volatile. CMS believes that because Medicare is the only payer for many CMHCs, many CMHCs have increased and decreased their charges in response to Medicare payment policies. CMS also believes that some CMHCs have manipulated their charges in order to inappropriately receive outlier payments. CMS wants to establish a payment method that would provide an incentive for CMHCs to stabilize their charges. If CMHC data continues to be unstable, CMS may only use hospital data in the future.

For 2006, CMS is proposing to apply a 15 percent reduction in the combined hospital-based and CMHC median per diem cost that was used to establish the CY 2005 partial hospitalization program APC. The proposed reduction would be a transitional measure and CMS will continue to monitor CMHC costs and charges and work with CMHCs to improve their reporting so that future payments can be calculated based on better data.

CMS is proposing to reduce the APC amount from $289 in CY 2005 to $241.57 for CY 2006, of which $48.31 is beneficiary coinsurance.

C. Proposed Conversion Factor Update for CY 2006

CMS is required to update the conversion factor annually and is required to update the 2006 conversion factor by the hospital inpatient market basket percentage increase for 2006 (forecasted to increase 3.2 percent). The 2005 conversion factor is $56.983. After adjusting the 2005 conversion factor for budget neutrality and applied offsets for pass-through payments and outliers, CMS applied the 3.2 percent increase, resulting in a proposed conversion factor for 2006 of $59.343.

D. Proposed Wage Index Changes for CY 2006

CMS plans to use the final version of the FY 2006 inpatient wage indices to determine the wage adjustments and copayment standardized amounts that will be published in the final OPPS rule for CY 2006. The percentage of the APC payment that is adjusted by the wage index will continue to be 60 percent.

This section discusses the use of Core Based Statistical Areas, occupational mix adjustment, and a wage index adjustment for "out migration" of hospital employees. Refer to the Proposed Rule for more information.

Addenda H through O include information on the various hospital wage indices and adjustments and hospital reclassifications and redesignations.

E. Proposed Statewide Average Default Cost-to-Charge Ratios

CMS uses cost-to-charge ratios (CCRs) to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under OPPS. CMS uses default CCRs for hospitals that do not have valid CCRs (e.g., new hospitals, hospitals with a CCR outside the CMS

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threshholds, and hospitals that have given up their all-inclusive rate status). CMS is proposing to update the default ratios for 2006 using the most recent cost report data. CMS describes the calculation of the 2006 default ratios and presents them in Table 3, Statewide Average Cost-to-Charge Ratios (pp. 42696 - 42698).

F. Expiring Hold Harmless Provision for Transitional Corridor Payments for Certain Rural Hospitals

When OPPS was implemented all hospitals were eligible for transitional corridor payments if their payments under OPPS were less than their payments would have been for the same services prior to OPPS (which were paid on a reasonable cost basis). For most hospitals these are temporary payments to ease the transition to OPPS. Cancer hospitals and children's hospitals receive transitional corridor payments on a permanent basis.

Rural hospitals with fewer than 100 beds were originally supposed to receive transitional corridor payments through CY 2003, but the transitional payments were extended through CY 2005. Transitional corridor payments to sole community hospitals located in rural areas were also extended through CY 2005.

Transitional corridor payments for rural hospitals with fewer than 100 beds and sole community hospitals located in rural areas will expire December 31, 2005.

G. Proposed Adjustment for Rural Hospitals

CMS has the authority to provide adjustments for rural hospitals if their costs are determined to be greater than urban hospitals.

This section describes two modeling approaches CMS used to determine rural versus urban costs: the "explanatory model" approach and the "payment model" approach. The explanatory model approach includes all variables that might impact cost in the regression analysis; the payment model approach only includes variables used in payment adjustments in the cost regression.

Based on their analysis, CMS determined that rural sole community hospitals are more costly than urban hospitals, but observed no significant difference between all other rural hospitals and urban hospitals.

CMS is proposing a 6.6 percent payment increase for rural sole community hospitals for CY 2006. The increase would apply to all services and procedures paid under OPPS with the exception of drugs and biologicals.

H. Proposed Hospital Outpatient Outlier Payments

For CY 2005, CMS targeted outlier payments to 2 percent of aggregate OPPS payments. To receive outlier payment, a hospital's costs must exceed 1.75 the APC payment amount and exceed the APC payment by $1,175 (the fixed dollar threshold). The fixed dollar threshold was introduced in 2005 to target outlier payments to high cost and complex procedures where a costly case could result in a significant financial loss. The 2005 outlier payment is equal to 50 percent of the amount by which the hospital's costs exceed 1.75 times the APC payment.

In 2005, community mental health centers (CMHCs) receive outlier payments when their costs exceed 3.5 times the APC payment rate. Outlier payments for CMHCs are equal to 50 percent of the amount by which the CMHC's costs exceed 3.5 times the APC payment.

In its March 2004 Report to Congress, MedPAC recommended that CMS eliminate the outlier policy; however, this would require a statutory change. MedPAC cited the following reasons for eliminating the outlier policy: the narrow definition of many of the services provided in hospital outpatient departments suggests that variability in costs should not be great; the distribution of outlier payment benefits some hospital groups more than others; the outlier policy is susceptible to "gaming" through charge inflation; and, the OPPS is the only ambulatory payment system with an outlier policy.

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For CY 2006, CMS is proposing to target outlier payments to 1 percent of aggregate payments, with .006 of the aggregate total payments allocated to CMHCs for partial hospitalization program services. As in 2005, hospital outlier payments would be triggered when costs exceed 1.75 times the APC payment amount, but CMS is proposing to raise the fixed dollar threshold to $1,575. The 2006 fixed dollar payment would be equal to 50 percent of the amount by which the hospital's costs exceed 1.75 times the APC payment. CMS is proposing to make outlier payments to CMHCs when the CMHCs costs exceed 3.45 times the APC payment rate; the outlier payment would be 50 percent of the amount by which the CMHC's costs exceed 3.45 times the APC payment rate.

I. Calculation of the Proposed National Unadjusted Medicare Payment

The national unadjusted APC payment rate is calculated by multiplying the proposed CY 2006 scaled weight for the APC by the proposed CY 2006 conversion factor. This section also explains how to calculate the proposed 2006 hospital specific payment rates.

J. Proposed Beneficiary Copayments for CY 2006

CMS is proposing to reduce the maximum unadjusted coinsurance amount to 40 percent of the total APC payment for 2006 and calendar years thereafter. By law the national unadjusted coinsurance amount cannot be less than 20 percent of the fee schedule amount.

III. Proposed Ambulatory Payment Classification (APC) Group Policies (pp. 42703 – 42713)

A. Background

CMS is required to review the components of OPPS and revise the relative payment weights at least annually. Since 2001, CMS is also required to consult with an outside panel of experts to review the APC groups and relative payment weights.

APCs are organized into groups that are homogenous both clinically and in terms of resource use. With some exceptions, items within an APC group cannot be considered comparable with respect to resource use if the highest median cost for an item in the group is more than 2 times greater than the lowest median cost for an item within the same group. This is referred to as the "2 times rule."

B. Proposed Changes - Variations within APCs

CMS and the APC Panel reviewed APCs that violate the "2 times rule." The APC Panel recommended moving 65 codes from their currently assigned APC. CMS agreed with 58 of the APC Panel recommendations, and is therefore proposing to reassign these 58 codes (see Table 7, pp. 42703-42704). CMS disagreed with the APC Panel recommendation for 7 codes; CMS proposed alternate solutions for resolving the 2 times rule violation for these codes.

This section also describes CMS's rationale for making exceptions to the 2 times rule and lists the proposed exceptions for 2006 (see Table 8, pp. 42705-42706).

C. New Technology APCs

CMS is proposing to add 10 New Technology APCs (APC 1491 - 1500). The new APCs would replace APC 1501 and 1538, which are both described as "New Technology, Level I, $0 - $50," (1501 is for status S codes; 1538 is for status T codes). The new APCs are broken down into $10 increments. Table 10 (p. 42707) lists CMS's proposed APC groups for codes that belonged to APCs 1501 and 1538.

CMS is proposing to require that an application for a code for a new technology service be submitted to the American Medical Association's CPT Editorial Panel before CMS will accept a New Technology APC application for review. CMS is proposing that a copy of the submitted CPT application be filed with CMS as a part of the application for a New Technology APC assignment under OPPS, along with CPT's letter acknowledging or accepting the coding application.

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Proposals for Proton Beam Therapy Codes:
CMS is proposing to move two CPT codes for proton beam therapy, 77523 and 77525, from APC 1510 to clinical APC 0667 (Level II Proton Beam Radiation Therapy).

Proposals for Stereotactic Radiosurgery Codes
CMS is proposing to make no changes to the APC placement of the following stereotactic radiosurgery codes: G0173, G0243, G0251, G0339 and G0440. CMS is proposing to discontinue codes G0242 and G0338 and to instruct providers to use CPT codes.

Proposals for Other Codes
CMS is proposing to move 10 additional codes from New Technology APCs to clinical APCs (see Table 11, p. 42709).

D. Proposed APC-Specific Policies

Hyperbaric Oxygen Therapy (APC 0659)
CMS describes their proposal for calculating the median cost for APC 0659. Although the hyperbaric oxygen therapy (HBOT) code C1300 is described per 30 minutes, some providers are billing per occurrence. Because hyperbaric oxygen therapy often takes 90 to 120 minutes, billing per occurrence results in an inflated median cost for the service. For CY 2006 ratesetting, CMS is proposing to exclude claims with only one unit of HBOT; this is the same ratesetting methodology that was used for CY 2005.

Allergy Testing (APC 0370)
A number of providers have expressed confusion on unit billing for allergy testing (95004-95078), most of which are assigned to APC 0370. Nine of the codes under APC 0370 are to be reported per test, 5 of the codes do not instruct providers to bill per test, causing confusion about whether to bill per test or per visit. CMS's review of their data shows that providers are sometimes billing per visit rather than per test even for the codes that specify per test. CMS believes this inaccurate coding would have resulted in an inflated median cost for APC 0370.

CMS is proposing to create a new APC, APC 0381 (Single allergy tests), and move all codes that instruct providers to specify the number of tests into this APC. Other codes would remain in APC 0370 (Allergy tests). A list of codes proposed for each APC is provided in Table 12 (pp. 42710-42711).

Stretta Procedure (APC 0422)
In 2005, CMS added code 43257 for the Stretta procedure which was grouped under APC 0422 (Level II Upper GI Procedures). Prior to 2005, the Stretta procedure was reported with code C9701 which was grouped in a new technology APC. Code 43257 includes all endoscopy procedures in the payment; C9701 did not. Because of these coding changes, CMS is proposing to use data from endoscopy codes 43234 or 43235 along with C9701 in their calculation of the median cost for APC 0422.

Vascular Access Procedures (APCs 0032, 0109, 0115, 0124, and 0187)
In 2004, new CPT codes were added for vascular access procedures. Because no data were available for these new codes, CMS crosswalked the newly created CPT codes to the deleted codes' APC assignments. CMS received comments requesting reassignment for some of these codes, but was reluctant to make changes until claims data became available. Based on review of 2004 claims data, CMS is proposing a new APC configuration for vascular access procedures and several related codes.

CMS is proposing to:

- move all procedures currently in APC 0187 (miscellaneous placement/repositioning) into more clinically appropriate APCs.
- create three new APCs: APC 0621, 0622, and 0623 (representing level I, II, and III vascular access codes)
- rename APC 0109 "Removal of implanted devices
- rename APC 0115 "Cannula/ access device procedures"

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A list of current and proposed APC assignments for vascular access procedures and related procedures is included in Table 13 (p. 42712).

E. Proposed Addition of New Procedure Codes

In the April update to the 2005 OPPS, CMS added 11 C codes. CMS is soliciting comment on the APC assignment of these services (see Table 14, p. 42713).

IV. Proposed Payment Changes for Devices (pp. 42713 - 42721)

A. Device-Dependent APCs

Device-dependent APCs are populated by codes that usually, but not always, require that a device be implanted or used to perform the procedure. This section describes CMS's proposed methodology for determining the APC medians for these services. In 2003, CMS removed the requirement to separately code for devices using C codes, believing that hospitals would continue to include the cost of these devices in their charges. However, after this coding change, hospitals did not always include the device costs in their charges. CMS reinstated the device coding requirement in 2005. Because of the coding problems in calendar years 2003 and 2004, CMS is proposing to adjust the median costs for the device-dependent APCs listed in Table 15 (pp. 42714-42716) to the greater of the median from claims data or 85 percent of the CY 2005 median used to set the CY 2005 payment rate.

B. APC Panel Recommendations Pertaining to APC 0107 and 0108

The median costs for APC 0107 (Implantation of cardioverter-defibrillator) and APC 0108 (insertion/replacement of cardioverter-defibrillator leads and insertion of cardioverter-defibrillator) have been adjusted each year since 2003 when pass-through payments for cardioverter-defibrillators expired.

CMS has used single procedure claims to establish the median costs for these APCs, which has resulted in establishing the median costs on a relatively small number of claims. Commenters have frequently told CMS that using single procedure median costs does not accurately reflect the costs of the procedures.

The APC Panel recommends that CMS package 93640 and 93641 into the APCs because these codes would never be correctly reported without a code in APC 0107 or 0108 and because packaging these services would result in more single procedure claims to be included in the analysis for determining the median costs.

The APC Panel also recommends that CMS treat CPT code 33241 as a bypass code when billed with procedures within APC 0107 and 0108 because the packaged costs are appropriately attributed to other codes.

CMS reviewed the APC Panel recommendations and believes the recommendations have significant merit, but is concerned with adopting these changes for CY 2006 due to the payment impacts on various groups.

CMS is proposing to set the medians for APC 0107 and 0108 at 85 percent of their CY 2005 payment medians. CMS requests public comment on the APC Panel recommendations.

C. Pass-Through Payments for Devices

By law, devices may be eligible for pass through payments for at least two but not more than three years. As proposed in the final rule for CY 2005, CMS will discontinue pass-through payment for C1814, C1818 and C1819 effective January 1, 2006; costs for these devices will be packaged into the costs of other procedures.

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D. Other Policy Issues Relating to Pass-Through Device Categories

CMS is proposing not to publish a list of APCs with device percentages for CY 2006 because of limitation in the CY 2004 OPPS data. CMS will reexamine their previous methodology for calculating the device percentages and offset amounts for the CY 2007 OPPS update.

When OPPS was implemented CMS established criteria for establishing a new category of devices for pass-through payment; one criterion was that the item had to be surgically inserted or implanted. CMS received comments that this requirement may prevent access to other innovative and less invasive technologies and asked that CMS change the criteria to allow pass-through payments for items introduced to the body through a natural orifice. CMS solicited additional comments in the final rule for CY 2005. After considering the comments, CMS is proposing to maintain their current criterion that a device must be surgically inserted or implanted, but is also proposing to modify the interpretation of this criterion to include items that are surgically inserted or implanted either through a natural orifice or surgically created orifice (such as through an ostomy), as well as those that are inserted through a surgically created incision.

V. Proposed Payment Changes for Drugs, Biologicals, and Radiopharmaceutical Agents (pp. 42721 – 42735)

A. Transitional Pass-Through Payment for Additional Costs of Drugs and Biologicals

By law, transitional pass-through payments for drugs and biologicals must be no less than two years and no longer than three years. CMS is proposing that the pass through status for 10 drugs and biologicals expire on December 31, 2005 (see Table 19, p. 42722). CMS is proposing to maintain the pass-through status for 14 drugs (see Table 20, p. 42723).

B. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

CMS is proposing to continue paying separately for drugs, biologicals, and radiopharmaceuticals whose per day cost exceeds $50, and to continue packaging the costs when the per day cost is less than $50. CMS is also proposing to continue to exempt oral and injectible 5HT3 anti-emetic products from the packaging rule. CMS will be evaluating the packaging thresholds for the 2007 OPPS update and requests comments.

CMS is proposing to pay ASP+6 percent for separately payable drugs and biologicals in CY 2006. For drugs other than radiopharmaceuticals where ASP information is unavailable, CMS proposes to use the mean costs from the CY 2004 hospital claims data to determine their packaging status and ratesetting.

CMS is proposing to discontinue low osmolar contrast material codes A4644-A4646 and instruct hospitals to use codes Q9945-Q9951. CMS is proposing to pay the Q codes separately using the ASP methodology.

CMS proposes to calculate per day costs of radiopharmaceuticals using mean unit cost from the CY 2004 data to determine packaging status. As a temporary 1-year policy, CMS proposes to pay for radiopharmaceutical agents that are separately payable based on the hospital's charge for each radiopharmaceutical agent adjusted to cost.

For CY 2006, CMS is proposing to begin collecting ASP data on all radiopharmaceutical agents. CMS is seeking comments on possible payment methods for CY 2007 if ASP data are still unavailable.

CMS is proposing to package 90393 and Q9953 because they were unable to determine ASP pricing for these codes.

MedPAC is required to submit a report on adjusting the APC rates for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. MedPAC developed seven drug categories for pharmacy and nuclear medicine handling costs, according

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to the level of resources used to prepare the products. MedPAC recommended that CMS establish separate budget neutral payments for handling costs and define a set of handling fee APCs.

CMS had some concerns about being able to appropriately assign drugs to MedPACs seven categories. For 2006, CMS is proposing to establish three distinct HCPCS C codes and three corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals, by combining several of the categories identified in the MedPAC report (see Table 24, p. 42730).

C. Proposed Coding and Billing Changes for Specified Covered Outpatient Drugs

CMS is proposing to base payment rates for drugs and biologicals and their pharmacy overhead costs on the ASP methodology that is used for payments in the physician office setting. Under the ASP methodology a single payment is calculated by considering prices for both brand and generic forms of the drug. Therefore, CMS is proposing to discontinue use of the C-codes that were created to represent brand drugs, and instruct hospitals to use the codes that represent generic drugs for both brand and generic drugs.

D. Proposed Payment for New Drugs, Biologicals, and Radiopharmaceuticals Before HCPCS Codes are Assigned

Historically, when hospitals billed for new drugs or biologicals that did not have a specific HCPCS code, they reported an unlisted HCPCS code and the costs were packaged under OPPS. When CMS created a temporary C code, these drugs and biologicals became eligible for pass-through payments.

For payments made after January 1, 2004, CMS is required to make payments for drugs and biologicals that do not yet have a specific HCPCS code at 95 percent AWP. In CY 2005, CMS instructed hospitals to bill HCPCS code C9399 (unclassified drug or biological) for these services, which caused the OCE to suspend for manual pricing. In CY 2005, CMS also expanded the payment policy to include payment for new radiopharmaceuticals without a specific HCPCS code.

CMS is proposing to continue the 2005 policy for payment of new drugs, biologicals and radiopharmaceuticals without HCPCS codes.

E. Proposed Payment for Vaccines

Because vaccine costs fluctuate considerably from year to year, CMS has paid hospitals, home health agencies and hospices on a reasonable cost basis for influenza and pneumococcal pneumonia vaccines since CY 2003. CMS is proposing to continue to pay these vaccines on a reasonable cost basis for CY 2006.

Hepatitis B vaccines are currently paid under clinical APCs that also include other vaccines. CMS is proposing to pay for all hepatitis B vaccines at reasonable cost, consistent with the payment method for influenza and pneumococcol pneumonia vaccines.

Currently, separately payable vaccines other than influenza and pneumoccocal are grouped into clinical APCs 355 and 356. For CY 2006, CMS is proposing to pay for each separately payable vaccine under its own APC to allow appropriate payment based on the ASP methodology.

F. Proposed Changes in Payment for Single Indication Orphan Drugs

In 2003, CMS identified 11 single indication orphan drugs, and paid for these drugs on a reasonable cost basis. In 2004, CMS added one code to the list of orphan drugs, established an APC group for each orphan drug, and paid for most of these drugs at 88 percent AWP. In 2005, CMS added two more codes to the list of orphan drugs, set payment for all single indication orphan drugs at the higher of 88 percent AWP or ASP+6 percent, and updated the payment rates quarterly.

For 2006, CMS is proposing to pay for single indication orphan drugs at ASP+6 percent. In addition, CMS is proposing to pay an additional 2 percent of the ASP scaled for budget neutrality to cover the handling costs of these drugs. CMS is proposing to update the payment rates quarterly.

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VI. Estimate of Transitional Pass-Through Spending in CY 2006 for Drugs, Biologicals and Devices (p. 42735)

This section discusses the proposed methodology for estimating total pass-through spending and whether there should be a pro rata reduction for transitional pass-through drugs, biologicals, radiopharmaceuticals, and categories of devices for CY 2006.

VII. Proposed Brachytherapy Payment Changes (pp.42736 – 42737)

This section discusses CMS's proposal for coding and payment for the sources of brachytherapy.

VIII. Proposed Coding and Payment for Drug Administration (pp. 42737 – 42740)

From OPPS implementation through 2004, CMS paid hospitals for drug administration services using Q codes that described services per visit and mapped to APCs paid on a per visit basis.

In 2005, CMS adopted new drug administration G codes for use in the physician's office setting and required the hospitals to begin using CPT codes instead of the Q codes to report drug administration. The CPT codes were not per visit codes. Hospitals were instructed to bill all relevant CPT codes, but the Outpatient Code Editor (OCE) collapsed the payments into a single per visit APC payment.

CMS anticipates that the 2005 G codes and the CPT codes used by hospitals to report drug administration in 2005 will be deleted in 2006 and that CMS will adopt new corresponding CPT codes for use by hospitals and in the physician's office setting.

CMS is proposing to map the new CPT codes to the existing drug administration APC groups (APC 0116, 0117, and 0120) as they did in 2005. As in 2005, hospitals would be instructed to bill all relevant CPT codes for services provided, but payment for services within the same APC would be collapsed by the OCE into a single per visit APC payment (unless there is a separate encounter on the same day).

Table 27, on pages 42738-42739 of the proposed rule, includes a crosswalk of the new drug administration codes to the drug administration APCs.

Vaccine Administration

Hospitals currently use codes G0008-G0010 for administration of vaccines that have specific statutory coverage.

CMS is proposing to make G0010 not payable under OPPS and instruct hospitals to use 90471 or 90472, which are currently packaged but are proposed to be paid through APC 0353 (Injection, Level II) in 2006.

Codes G0008 (administration of influenza virus vaccine) and G0009 (administration of pneumococcal vaccine) are currently paid on a reasonable cost basis. CMS is proposing to make APC payments for G0008 and G0009; the payment would be the same as payment for vaccines paid by APC 0353, but a separate APC is needed (APC 0350) for claims processing purposes because these codes are exempt from deductibles and coinsurance.

CMS is proposing to change the status for codes for vaccine administration involving physician counseling (CPT 90465-90468) from packaged to not paid under OPPS. CMS does not believe provision of physician counseling significantly affects hospital resource requirements, so they are proposing that hospitals use CPT codes 90471-90474 instead.

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CMS is proposing to change CPT codes 90471-90472 from packaged to paid by APC 0353 and to change codes 90473-90474 from not paid under OPPS to APC 1491.

Code(s)	Administration code(s) for:	2005 Payment	Proposed 2006 (status indicator)	Notes
G0008 – G0009	Vaccines exempt from deductibles and coinsurance	Reasonable Cost	APC 0350 (X)	Same payment as APC 0353
G0010	Hepatitis B vaccine	APC 0355	Not paid under OPPS (B)	Use codes 90471-90472
90465 - 90468	Vaccines involving physician counseling	Packaged	Not paid under OPPS (B)	Use codes 90471-90474
90471 - 90472	Vaccine by injection	Packaged	APC 0353 (X)	
90473 - 90474	Vaccine by intranasal or oral	Not paid under OPPS	APC 1491 (S)	

IX. Hospital Coding for Evaluation and Management Services (p. 42740)

CMS plans to propose coding guidelines for emergency department and clinic visits in an upcoming proposed rule. The public can join a listserv to be notified about the proposed guidelines. CMS anticipates providing a minimum notice of 6 to 12 months prior to implementing the new evaluation and management codes and guidelines to allow time to educate clinicians and coders on the guidelines and time for hospitals to modify their payment systems.

To join the listserv, go to http://www.cms.hhs.gov/medlearn/listserv.asp and follow the directions to the OPPS listserv.

X. Proposed Payment for Blood and Blood Products (pp. 42740 – 42742)

Since OPPS was implemented in 2000, CMS has made separate payments for blood and blood products through APCs rather than packaging them into payments for associated procedures. Because CMS had limited data, the initial 2000 APC payment rates were based on external data provided by commenters. The rates for 2001 and 2002 were based on the 2000 rates and updated for inflation. In 2003, CMS began using their own claims data to determine payment rates, but limited decreases from 2002 to 2003 to approximately 15 percent. In 2004, based on APC Panel recommendations and concerns from commenters, CMS froze the APC payment rates at the 2003 levels.

In 2005, CMS established new APCs that allowed each blood product to be assigned its own separate APC. Prior to 2005, several APCs contained multiple blood products that did not necessarily have similar costs. In response to comments that the cost to charge ratios used by CMS to determine the median payment levels were too low, CMS developed a new way to calculate the median payments for blood products that takes into account the differences in cost to charge ratios for hospitals with and without blood-specific cost centers. In 2005 CMS also developed a new calculation method for median payments for low-volume blood products to reduce the potential that these blood products are inappropriately priced due to a few billing or coding errors.

For 2006, CMS is proposing to continue to make separate payments for blood and blood products through individual APCs for each product using the same calculation method for median payments that was established in 2005. CMS is proposing to limit any decreases to median payments to 10 percent compared to the 2005 rates.

CMS recognizes that some of the decreases in the median payments may be the result of hospitals being unclear about what costs should be included in their charges for blood products. CMS clarified their billing requirements in a March 2005 transmittal and expects that this instruction will help hospitals to more fully

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include all appropriate costs for providing blood products. CMS expects that their 2005 claims data, which will be used to determine the 2007 OPPS rates, will more accurately reflect hospitals costs.

CMS is also proposing to change the OPPS status indicator for CPT 85060 (Blood smear, peripheral, interpretation by physician with written report) from "X" (separately paid under OPPS) to "B" (not paid under the OPPS). CMS considers this service bundled into the hematology lab service (e.g. 85007, 85008), which is paid separately under the Clinical Laboratory Fee Schedule.

XI. Proposed Payment for Observation Services (pp. 42742 – 42745)

Prior to OPPS implementation, CMS paid for observation services on a reasonable cost basis. When OPPS was initially implemented, CMS packaged all observation services. In 2002, CMS began paying separately for observation services for chest pain, congestive heart failure and asthma if the CMS criteria were met.

In 2005, CMS removed their requirement of mandated diagnostic tests and clarified their instructions on calculating observation care time. CMS also reviewed the list of diagnoses that were separately payable for observation services, but did not make any changes.

For 2006, CMS is proposing to continue applying the 2005 criteria that determine when a hospital receives separate payment for observation care provided to patients with chest pain, congestive heart failure, and asthma. The APC Panel recommended expanding the list of diagnoses for which observation services are payable, but CMS believes it is premature to make changes to the list. CMS reviewed their claims data and found problems with inconsistent hospital billing, with some hospitals billing observation services per day and others billing per hour as instructed to do when reporting G0244. CMS wants additional claims experience before making changes to their payment policies for observation care.

In response to APC Panel recommendations and to comments regarding the administrative burden of billing for observation services, CMS is proposing to change the codes hospitals report for observation services and to change the point at which a payment determination is made. Rather than requiring hospitals to determine prior to claims submission whether the patient condition and services furnished meet the criteria for payment, OPPS claims processing logic would determine whether observation services are separately payable.

CMS is proposing to delete HCPCS codes G0244, G0263 and G0264 and to create two new G codes (code numbers to be determined).

2005 Code	Description	2006 Code	Description
G0244	Observation care provided by a facility to a patient with chf, chest pain, or asthma, minimum eight hours	GXXXX	Hospital observation services, per hour
G0263	Direct admission of patient with diagnosis of congestive heart failure, chest pain or asthma for observation services that meet all criteria for G0244	GYYYY	Direct admission of patient for observation care
G0264	Initial nursing assessment of patient directly admitted to observation with diagnosis other than chf, chest pain or asthma or patient directly admitted to observation with diagnosis of chf, chest pain or asthma when the observation stay does not qualify for G0244		

XII. Procedures that will be Paid Only as Inpatient Procedures (pp. 42745 – 42747)

Inpatient List

The "inpatient list" specifies services that CMS only pays when provided in an inpatient setting because of the nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or the physical condition of the patient.

CMS has established the following criteria for removing a procedure from the inpatient list:

- Most outpatient departments are equipped to provide the services to the Medicare population;

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- The simplest procedure described by the code may be performed in most outpatient departments;
- The procedure is related to codes that CMS has already removed from the inpatient list;
- CMS has determined that the procedure is being performed in multiple hospitals on an outpatient basis; or
- CMS has determined that the procedure can be appropriately and safely performed in an ambulatory surgical center (ASC) and is on the list of approved ASC procedures or proposed by CMS for addition to the ASC list.

CMS is proposing to remove 25 codes from the inpatient list. CMS assigned 23 of the procedures to clinically appropriate APCs. The other two procedures were for anesthesia services, which are packaged under OPPS and are not separately payable. Refer to Table 31 on page 42746 of the proposed rule for the list of codes CMS is proposing to remove from the inpatient list.

CMS reviewed the following codes and is proposing not to remove them from the inpatient list: 33420, 59856 and 65273.

Ancillary Outpatient Services When Patient Expires (Modifier –CA)

In 2003 CMS established the modifier –CA to be used when providing services on the inpatient list on an emergency basis to resuscitate or stabilize a patient with an emergent, life-threatening condition and the patient dies before being admitted as an inpatient. In 2003, services that were otherwise payable as outpatient services that were billed on the same claim as a service billed with modifier –CA were paid under APC 0977 (New Technology Level VIII, $1000 -$1250). In 2004, CMS created APC 0375 (Ancillary Outpatient Services When Patient Expires, $1,150) to pay for these services. In 2005 CMS continued to pay for these services with APC 0375 with a median payment rate of $3,217.47.

CMS is not proposing any payment policy changes for 2006 for ancillary outpatient services when the patient expires. The calculated median cost for APC 0375 in calendar year 2006 is $2,528.61.

CMS is concerned with the large increase in the volume of hospital claims billed with the –CA modifier from 2003 to 2004. CMS's clinical review of these services indicated that hospitals were not always billing these services appropriately. CMS is concerned that some reported procedures were not for patients with emergent, life-threatening conditions. CMS will continue to closely monitor use of the –CA modifier to assess whether a proposal to change payment policies for APC 0375 would be warranted in the future or whether hospitals require further education regarding the correct use of modifier –CA.

XIII. Proposed Indicator Assignments (pp. 42747 – 42748)

Each APC has a status indicator. Each HCPCS code has the same status indicator as the APC group to which it belongs. The status indicator determines whether a code is payable under OPPS and whether particular OPPS policies apply to the code. The APC status indicator assignments are in Addendum A, the HCPCS status indicator assignments are in addendum B, and the status indicator definitions are in Addendum D1 of the proposed rule.

CMS is proposing two new status indicators for 2006:

M – Items and services not billable to the fiscal intermediary (services are only billable to carriers and are not paid under OPPS)

Q – Packaged services subject to separate payment under the OPPS payment criteria (separate payment is made if criteria are met)

CMS is requesting comments on the appropriateness of the assigned status indicators.

XIV. Proposed Nonrecurring Policy Changes (pp. 42748 – 42753)

Proposed Payments for Multiple Diagnostic Imaging Procedures

CMS is proposing to make a 50 percent reduction in OPPS payments for second and subsequent imaging procedures performed in the same session for services within the same family of imaging procedures. CMS

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is proposing 11 imaging families defined by imaging modality and contiguous body area (see table below). The payment reduction would not apply across families.

CMS believes that duplicate payment is currently being made for the technical component of multiple diagnostic imaging services, particularly when contiguous body parts are viewed in a single session.

Family #	Imaging Modality	Body Area	Codes in Family
Family 1	Ultrasound	Chest / Abdomen / Pelvis-Non-Obstetrical	76604-76778, 76830-76857
Family 2	CT and CTA	Chest / Thorax / Abd / Pelvis	71250-71275, 72191-72194, 74150-74175, 75635, 0067T
Family 3	CT and CTA	Head / Brain / Orbit / Maxillofacial / Neck	70450-70498
Family 4	MRI and MRA	Chest / Abd / Pelvis	71550-71555, 72195-72198, 74181-74185
Family 5	MRI and MRA	Head/Brain/Neck	70540-70553
Family 6	MRI and MRA	Spine	72141-72158
Family 7	CT	Spine	72125-72133
Family 8	MRI and MRA	Lower extremities	73718-73725
Family 9	CT and CTA	Lower extremities	73700-73706
Family 10	Mr and MRI	Upper extremities and joints	73218-73223
Family 11	CT and CTA	Upper extremities	73200-73206

Interrupted Procedure Payment Policies (Modifiers -52, -73, and -74)

Since OPPS implementation, CMS has required hospitals to report modifiers -52, -73 or -74 to indicate procedures that were terminated before their completion.

Modifier -52 indicates partial reduction or discontinuation of services that do not require anesthesia. There is currently no payment reduction when modifier -52 is reported. CMS data show that modifier -52 is used infrequently and is typically reported for radiology and imaging services.

CMS is proposing to pay 50 percent of the APC payment amount for a discontinued procedure that does not require anesthesia where modifier -52 is reported. CMS believes this proposed reduction would appropriately recognize the hospital's costs involved with the delivery of a typically reduced service, similar to the CMS policies for interrupted procedures that require anesthesia.

Modifier -73 is to be used for procedures requiring anesthesia where the patient was taken to the treatment room and the procedure was discontinued before anesthesia administration. There is a 50 percent payment reduction when modifier -73 is reported. Circumstances that require the use of modifier -73 occur infrequently.

The APC Panel recommended that CMS make full payment when modifier -73 is reported because significant resources are expended to prepare the patient and treatment or operating room for the procedure. CMS disagrees with the APC Panel recommendation and believes that hospitals realize significant savings in these modifier -73 situations. CMS is proposing to retain their 50 percent payment reduction for services reported with modifier -73.

Modifier -74 is to be used for procedures requiring anesthesia where the patient was taken to the treatment room and the procedure was discontinued after anesthesia administration. There is no payment reduction when modifier -74 is reported.

CMS is considering applying a payment reduction for interrupted procedures in which anesthesia was to be used (and may have been administered) and the procedure was initiated. The APC Panel recommended that CMS continue to pay these services at 100 percent of the APC payment. CMS is soliciting comments regarding the costs incurred by providers in these cases and is specifically interested in comments on the clinical circumstances in which modifier -74 is used and the degree to which hospitals experience cost

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savings. CMS is interested in whether devices and specialized equipment that would have been used in a complete procedure are not used when the service is discontinued and what stage the decision to discontinue the procedure is made.

XV. OPPS Policy and Payment Recommendations (p. 42753)

This section outlines the Medicare Payment Advisory Commission (MedPAC) recommendations from their March 2005 report to Congress and references the APC Panel recommendations and the GAO hospital drug acquisition cost survey.

XVI. Physician Oversight of Mid-Level Practitioners in Critical Access Hospitals (pp. 42753 – 42754)

CMS is proposing to defer to State law regarding review of records for outpatients cared for by nonphysician practitioners in Critical Access Hospitals. If State law allows the practitioner to practice independently, CMS would not require physicians to review and sign medical records for their patients. For those states that do not allow nonphysician practitioners to practice independently, CMS proposes to continue to require that a physician review and sign a sample of outpatient records at least once every two weeks. The Critical Access Hospital would determine the sample size of the reviewed records.

XVII. Files Available to the Public via the Internet (p. 42754)

The data referenced for addendum C and addendum P were not included in the proposed rule because of their size, but are available on CMS's web site at www.cms.hhs.gov/providers/hopps.

XVIII. Collection of Information Requirements (pp. 42754 – 42755)

This section provides information on where to send comments regarding information collection and recordkeeping requirements. The only issue in this proposed rule that affects information collection requirements is the proposal regarding physician oversight of mid-level practitioners in Critical Access Hospitals (see section XVI).

XIX. Response to Public Comments (p. 42755)

CMS will respond to all comments received by 5:00 pm on September 16, 2005 in the preamble to the OPPS final rule.

XX. Regulatory Impact Analysis (pp. 42755 – 42762)

The changes in the proposed rule would affect all classes of hospitals. Some hospitals experience significant gains and others less significant gains, but all hospitals would experience positive updates in OPPS payments in CY 2006.